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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,186	10/22/2003	John Girdner Atwood	07759-019004	6805

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EXAMINER
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BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/691,186

Applicant(s)

ATWOOD ET AL.

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 219-259 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 219-222, 231-242 and 251-259 is/are rejected.
- 7) ☒ Claim(s) 223-230 and 243-250 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/2006 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1744

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 219-222, 231-242 and 253-259 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al.(WO 89/09437) in view of Van Nostrand (Van Nostrand's Scientific Encyclopedia).

With respect to claim 219, the reference of Dean et al. discloses an apparatus (10) that includes a heating and cooling system (12,14); a sample block (16) including at least one well (17). The sample block is capable of thermal contact with the heating and cooling system (12,14). The apparatus includes means for determining the temperature of the block (See pages 6-7 and element (22)). The apparatus includes a computing apparatus (See sub-housing (18) and page 5, line 24, to page 6, line 3) to control the heating and cooling system.

While the reference of Dean et al. discloses that "the microprocessor being programmed to anticipate the time lag between the support temperature and the reaction temperature if only the support is sensed" (See page 4) and the reference discloses the use of an algorithm for predicting the sample temperature based on the block temperature (See page 15), the reference is silent as to the specific algorithm employed to predict the sample temperature based on the block temperature.

The reference of Van Nostrand discloses a conventional algorithm (Newton's Law of Cooling, See page 1116) used to predict the temperature of a body as a function of time based on

Art Unit: 1744

the temperature of a surrounding medium. The reference of Van Nostrand additionally discloses that the use of numerical integration is known in the art to solve a differential equation when initial values are known (Euler Method for Numerical Solution of a Differential Equation, See page 620).

In view of the disclosure of the reference of Dean et al. to employ an algorithm to relate the temperature of the sample to that of the block temperature and in view of the algorithm and numerical integration disclosed by the reference of Van Nostrand, it would have been obvious to one of ordinary skill in the art to employ the temperature function of the reference of Van Nostrand to predict the temperature of the sample of the reference of Dean et al. for the known and expected result of employing an art recognized differential equation and numerical integration to predict the temperature of a body relative to the known temperature of another body which is required of the algorithm discussed of the reference of Dean et al. Note the algorithm recited in claims 219 is merely a numerical integration of the differential equation of the function disclosed by the reference of Van Nostrand which is conventional in the art.

With respect to claim 220, as discussed in the reference of Van Nostrand, one of ordinary skill in the art would recognize that the time constant is based on the size and material properties of the sample and block components.

With respect to the input device of claim 221, the reference of Dean et al. discloses the use of a keyboard as an input device (See pages 7 and 11).

Claims 239-241 are obvious over the combination of the references of Dean et al. and Van Nostrand for the same reasons set forth with respect to claims 219-221 above.

Art Unit: 1744

With respect to claims 222 and 242, while the reference of Dean et al. discloses a block (16) with wells (17), the reference is silent as to the specific dimensions of the wells.

However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the size of the wells based merely on the desired size sample tubes intended to be used in the temperature control system.

With respect to the limitations of claims 231-238 and 251-257, while the reference of Dean et al. discloses that the device includes an input device (keyboard) and that the device is required to operate at a specific temperature/time profile, the reference is silent as to the specific various control parameters with respect to the temperature control in terms of overshoot, undershoot, tube size, sample volume, etc.

However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum control parameters to perform a desired PCR reaction based on considerations such as the specifics of the reaction to be performed in terms of the sample source and the reagents employed while maintaining the efficiency of the reaction system.

With respect to claims 258 and 259, the algorithm suggested and discussed above is capable of functioning when using a time interval of 0.2 seconds. Note claims 219 and 239 are apparatus-type claims rather than method claims.

***Allowable Subject Matter***

6. Claims 223-230 and 243-250 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 223-230 and 243-250, while the prior art of record discloses an automated system for controlling the temperature of a liquid sample which includes a sample block for holding the sample, a computer, heating and cooling control and a temperature measurement device for determining the temperature of the sample by sensing the temperature of the block, the prior art of record fails to teach or fairly suggest the claimed enclosure for the sample block which defines the recited central region, edge regions, manifold regions and manifolds.

***Response to Arguments***

8. With respect to the rejection of Claims 219-222, 231-242 and 253-259 under 35 U.S.C. 103(a) as being unpatentable over Dean et al.(WO 89/09437) in view of Van Nostrand (Van Nostrand's Scientific Encyclopedia), Applicants argue that the rejection is improper for a number of reasons as set forth below.

Applicants argue that the Examiner is required to give full faith and credit to the search and examination of a previous Examiner (See pages 15-16 of the response filed 2/9/2006).

In response, these comments are not found to be persuasive because the instant application is not the same application as that examined by the previous examiner. The instant application is a continuation of application 09/481,552 which is a division of application 08/422,740 which is a continuation of application 08/201,859 which is a division of application 07/871,264. Additionally the claims filed in the instant application were not identical to the claims filed in application 07/871,264 and currently are not identical in scope. As a result, the Examiner in the instant application was required to perform a new search and/or reconsider the prior art of record in view of the difference in the claim language.

Applicants argue neither the references of Dean et al. nor Van Nostrand provide the motivation (See pages 16-17 of the response filed 2/9/2006) to modify Dean et al. to include a numerical integration of Newton's Law of Cooling. Applicants stress that in view of the specific disclosure of Van Nostrand that more accurate methods are preferred for solving a differential equation, one of ordinary skill in the art would not be motivated to modify Dean et al. with the algorithm and method disclosed in Van Nostrand.

In response, the Examiner disagrees. The reference of Van Nostrand has been cited as evidence that the level of skill in the art is at a level such that one of ordinary skill in the art would be capable of deriving the equation provided in the instant claims. Applicants appear to take the position that the level of skill in the art is at a level that one of ordinary skill in the art would not be capable of deriving the equation of the instant claims in view of Newton's law of cooling and elementary differential equations and numerical integration. The motivation for deriving the equation is actually provided in the reference of Dean et al. Specifically the reference of Dean et al. states that "the microprocessor being programmed to anticipate the lag



Art Unit: 1744

between the support temperature and the reaction temperature if only the support is sensed” (See the last paragraph of page 4) and the reference of Dean et al. discusses the programming of the temperature control of the device (See paragraph “10.” page 15). The Examiner is of the position that the lack of details regarding the specifics of the programming and/or algorithms employed is indicative that the author of the specification of Dean et al. considered the programming and/or algorithms within the purview of one having ordinary skill in the art. The Examiner also points to equation (6) on page 53 of the instant application which is the same as that shown in the reference of Van Nostrand with respect to Newton’s’ Law of Cooling. The Examiner also notes that Applicants do not argue that the equations are different but that there is no motivation to employ the teachings of Van Nostrand to modify the reference of Dean et al.

Applicants argue that the reference of Dean et al. fails to teach or suggest the claimed formula and terms of the formula and determining the temperature of a liquid sample mixture (See page 17 of the response filed 2/9/2006).

In response, as recited in the prior art rejection of record, while the reference of Dean et al. does not specifically disclose the claimed formula, the reference discloses determining the temperature of a liquid sample mixture and discloses that the computer or microprocessor is programmed to determine or predict the temperature of the sample based on the temperature of the sample plate or support (See the last paragraph of page 4 and paragraph “10.” page 15). As stated previously, the Examiner is of the position that one of ordinary skill in the art is capable of deriving the claimed formula and terms based on the disclosure of Dean et al. and the disclosure of Van Nostrand.

Applicants argue that the combination of the references of Dean et al. and Van Nostrand fail to teach or suggest sample temperature in the first sample interval or sample temperature in the second sample interval and/or tau which is a function of the thermal characteristics of the apparatus (See pages 17-18 of the response filed 2/9/2006).

In response, the Examiner is of the position that the derived equation as suggested by the reference of Van Nostrand provides the sample intervals discussed by Applicants. Specifically the numerical integration disclosed by the Euler method. Additionally, the Examiner is of the position that one of ordinary skill in the art recognizes that “A” in the equation of Newton’s Law of Cooling is equivalent to “tau” of the instant claims and is related to the thermal characteristics of the apparatus. Note Van Nostrand recites “A is a constant depending on the size, shape, material, and surface of the body”.

With respect to claim 220, Applicants argue that the combination of the references of Dean et al. and Van Nostrand fail to teach or suggest tau as required in claim 220 (See page 18 of the response filed 2/9/2006).

In response, while the combination of the references does not specifically recite this claim language, the Examiner is of the position that in the absence of a showing of criticality and/or unexpected results, one of ordinary skill in the art is capable of determining “tau” based on the physical characteristics of the system in which Newton’s Law of Cooling is applied.


### ***Conclusion***

Art Unit: 1744

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB